2001 National Survey of Hospital Coagulation Laboratory Practices:
Quality Assurance

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Introduction

Hospital clinical laboratories play an important role in healthcare; and as documented in this survey, an estimated 97% of hospital laboratories reported performing coagulation tests. Coagulation tests are known to be vital to the diagnosis, treatment and management of bleeding and hypercoagulability disorders, and the majority of them are performed to screen for coagulation disorders or to monitor therapeutic anticoagulant therapy. In response to the uncertainty surrounding coagulation testing practices, we conducted this survey of hospital coagulation laboratories in the US, and chose hospitals as the testing environment to address a broader spectrum of in-house testing practices not subject to observation in physician office laboratories or other point-of-care testing sites. The purpose of this survey was to evaluate the availability of coagulation tests, assess various pre-analytical, analytical and post-analytical stages of the testing process, and evaluate some testing practices critical to clinical management of patients. This paper presents reported practices relating to coagulation quality assurance (QA) practices.
The survey used and a summary of our findings can be found at http://www.phppo.cdc.gov/mlp/coag2001.asp.

Methods

A group of coagulation laboratory experts and survey methodologists assisted the CDC in the development as well as the evaluation of the content and format of this 2001 survey of hospital coagulation laboratory directors (response rate, 79%). Furthermore, several versions of the survey were pilot tested in 9 hospital coagulation laboratories before its final dissemination. From a sampling frame of institutions listed in the 1999 directory of the American Hospital Association (AHA), we randomly selected 800 hospitals (sampling rate, 14%), and assessed practices in their coagulation laboratories. This sampling frame is not limited to the AHA members and it includes 95% of all hospitals as indicated by the Online Survey, Certification and Reporting database of CLIA-registered hospital laboratories. Participants had the option of responding via Internet, and 20 (3%) did so. Inconsistent responses were excluded from data analysis.

Results

Response rate. We received returned surveys from 632 institutions, resulting in a response rate of 79%.
Performance of coagulation tests. Of the 629 responding to this question, 612 (97%) reported performing coagulation testing.

Rejection of Specimens

Rejection criterion	Number (%) of Hospital Laboratories
Specimens collected via indwelling catheter.*	186 (32%)
Specimens not having a medical record number	263 (45%)
Specimens stored at an inappropriate temperature	502 (85%)
Hemolyzed specimens	518 (86%)
Requisition and specimen having conflicting Patient information	547 (92%)
Specimen transport time exceeding recommended time frame	549 (92%)
Insufficiently labeled specimen containers	603 (99%)
Improperly anti-coagulated specimens	604 (99%)
Clotted specimens	612 (100%)

*It has been recommended that, due to the presence of anticoagulants at such collection sites, specimens used for monitoring heparin therapy should be collected from a different extremity than the one used for heparin infusion (*Arch Pathol Lab Med.* 1998;122:782-798).

Circumstances when a Coagulation Test was Usually Repeated

Circumstance	Number (%) of Hospital Laboratories
When results were outside of the reference ('normal') interval	87 (16%)
When a result did not agree with previous results ('Delta Check')	424 (73%)
When results were critical ('panic') values	571 (95%)
When results were outside instrument technical ranges	582 (98%)
When control(s) was/were out of range	584 (98%)

Other Quality Assurance (QA) Procedures

Respondents usually took the following QA steps:

Management of results and information
- patient's previous results checked (Delta Check), 76% (n = 456);
- instrument printout compared to reported value, 82% (n = 487);
- specimen label and requisition form matched, 90% (n = 532);
- patient information on specimen tube and laboratory-generated labels matched, 93% (n = 558).

Instruments and analytical methods*
- new analytical methods validated, 98% (n = 587);
- calibration of all instruments periodically verified, 99% (n = 597).

*According to CLIA regulations, calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. [CDC. *CLIA Subpart K Quality Systems for Non-Waived Testing.* http://www.phppo.cdc.gov/clia/regs2/subpart_k.asp#493.1255 (Accessed, September 2003). Sec. 493.1255].

Running specimens/controls in duplicate*
- controls run in duplicate, 38% (n = 229);
- specimens run in duplicate, 39% (n = 235).

*CLIA requires that patient and control specimens be tested in duplicate for manual coagulation tests; duplicate testing is not required for automated coagulation tests [CDC. *CLIA Subpart K Quality Systems for Non-Waived Testing.* http://www.phppo.cdc.gov/clia/regs2/subpart_k.asp#493.1269 (Accessed, September 2003). Sec. 493.1269(b), (c)].

Critical (Panic) values
- critical (panic) values reviewed,99% (n = 596); 99% (n = 596);
- critical (panic) values brought to immediate attention of the clinician,99% (n = 598). * 99% (n = 598).

*According to the CLIA regulations, the laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test result when any test result indicates an imminently life-threatening condition, or panic or alert values. [CDC. *CLIA Subpart K Quality Systems for Non-Waived Testing.* http://www.phppo.cdc.gov/clia/regs2/subpart_k.asp#493.1291 (Accessed, September 2003) Sec. 493.1291(g)].

Other QA check
- plasma checked for platelet count after centrifugation, 23% (n = 137).

Concluding Remarks

Limitations

Various laboratory practices noted in this survey are those that have been reported; and like any other surveys, they may not reflect actual practices. Surveys are subject to framing biases which can be reduced (e.g., by pilot testing) but not totally avoided.

Generalizability

Due to the high response (79%) and sampling (14%) rates, results of this survey appear to be generalizable.

In conclusion, we found substantial departure from certain accepted laboratory QA practices which may result in adverse events. Further studies are necessary to determine to what extent not following accepted laboratory QA practices contributes to adverse patient outcomes. There appears to be a need to identify and communicate the reasons for lack of adherence to QA practices in an attempt to promote accepted standards of laboratory practice.